

**IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA**

KINETIC CONCEPTS, INC., KCI)
LICENSING, INC., KCI USA, INC.,)
KCI MEDICAL RESOURCES, MEDICAL)
HOLDINGS LIMITED, KCI)
MANUFACTURING and WAKE FOREST)
UNIVERSITY HEALTH SCIENCES,)
)
Plaintiffs,)
)
v.) No. 1:08CV00918
)
CONVATEC INC.,)
BOEHRINGER WOUND SYSTEMS, LLC,)
and BOEHRINGER TECHNOLOGIES, LP,)
)
Defendants.)

MEMORANDUM OPINION AND ORDER

This matter comes before the Court on "Defendants' Motion for Leave to File Their Amended Answer" (Docket Entry 62), in which Convatec Inc., Boehringer Wound Systems, LLC, and Boehringer Technologies, LP (collectively, "Defendants") seek to add an affirmative defense, as well as related counterclaims and prayer for relief, alleging that Plaintiffs committed inequitable conduct to procure patents at issue in the case. For the reasons that follow, the Court finds that Defendants' proposed amendment is not futile, but defers entry of an order permitting said amendment to allow Defendants an opportunity to correct what the Court deems largely technical defects in the proposal.

I. BACKGROUND

In this action, Plaintiffs have brought a claim against Defendants for patent infringement related to a wound treatment system. (Docket Entry 4 at ¶¶ 25-29.) Plaintiffs' therapy, the Vacuum Assisted Closure System, incorporates various patents, including U.S. Patent No. 5,645,081 ("'081"). (Id. at ¶¶ 15, 17.) Defendants filed an Answer setting forth seven affirmative defenses, as well as compulsory counterclaims of non-infringement and invalidity. (Docket Entry 19 at 6-13.) In their affirmative defense and counterclaims as to invalidity, Defendants alleged that the patents at issue, including the '081 patent, were "invalid for failure to comply with the patent laws, including, but not limited to, 35 U.S.C. §§ 101-103, and/or 112." (Id. at 7, 11-12.)

This Court, per United States Magistrate Judge Wallace W. Dixon, thereafter entered a Joint Stipulated Scheduling Order that set various discovery time limits, as well as a November 3, 2009 "deadline for leave to amend pleadings," after which date, "the court will grant leave for good cause." (Docket Entry 37 at 1.) On October 28, 2009, counsel for Defendants e-mailed Plaintiffs' counsel a copy of a proposed amended answer and advised that said proposal "adds an Eighth Affirmative Defense concerning inequitable conduct, including corresponding counterclaims and prayer for relief." (Docket Entry 62-2 at 3.) Defendants' counsel explained that he "intend[ed] to seek leave of the Court to file this Amended

Answer on or before November 3" and asked if Plaintiffs' counsel "will consent to the filing of Defendants' Amended Answer." (*Id.*)

Two days later, Plaintiffs' counsel responded by e-mail that she had "forwarded [said] request to [her] client and [was] waiting on a response." (*Id.*) In the same message, Plaintiffs' counsel asked for the position of Defendants' counsel as to Plaintiffs' previously "proposed scheduling changes . . . , which include an extension of the deadline to amend pleadings to a time after the parties have had an opportunity to accomplish greater discovery." (*Id.*) Defendants' counsel promptly replied that his "client [wa]s still considering Plaintiffs' proposed extension of about 6 months for amended pleadings," but noted "reservations" about "an extension of that length," as well as "concern[] that even if the parties agree to a schedule extension, the Court may not." (*Id.* at 2.) He then re-iterated his need to know if Plaintiffs would consent to the filing of the proposed amended answer. (*Id.*) Plaintiffs' counsel thereafter described her clients' position on that issue as follows: "If Defendants will agree to extend the deadlines for discovery, which will be needed for the new issues raised in the amended answer, [Plaintiffs] will not object to the motion for leave to amend." (*Id.*)

Several days later, Defendants timely filed the instant motion with an attached copy of their proposed amended answer. (Docket Entry 62.) In the motion, Defendants noted that they had

"contacted Plaintiffs to seek their consent to Defendants' Motion, and Plaintiffs' gave their consent in principle, but only if Defendants agreed to Plaintiffs' request to extend the discovery deadlines." (*Id.* at 2.)¹ Plaintiffs thereafter responded in opposition to Defendants' instant motion, not on the grounds that Plaintiffs would need additional discovery time to explore "the new issues raised in the amended answer" (as they previously had communicated to Defendants) (Docket Entry 62-2 at 2), but instead "because the proposed pleading fails to meet the requirements for pleading fraud under [Federal Rule of Civil Procedure] 9(b) and because there is no set of facts that Defendants can plead to state a claim for fraud on the Patent Office." (Docket Entry 69 at 2.)²

As Defendants' counsel noted when he forwarded the proposed amended answer to Plaintiffs' counsel, Defendants seek to add an Eighth Affirmative Defense (with related counterclaims and prayer for relief) alleging that Plaintiffs "committed inequitable conduct

¹ According to Defendants, "[t]he parties [we're] continuing to discuss extending discovery deadlines, but ha[d] not yet reached agreement." (Docket Entry 62 at 2.) In fact, the parties never reached agreement on this subject and Plaintiffs moved separately for a scheduling order amendment. (Docket Entries 70 and 75.) Defendants opposed that request, although they expressed a willingness to accept the proposed extensions of case management deadlines if Plaintiffs joined Defendants' request for an early claim construction hearing. (Docket Entry 77 at 1.) As to the proposed amended answer, Plaintiffs apparently did not communicate a change in their position from a conditional objection based on prejudice (i.e., the need for additional discovery time) to a substantive objection (i.e., that the proposed amendment was futile) before Defendants filed the instant motion. (See Docket Entry 62 at 5 ("Plaintiffs have not argued that Defendants' amendment of inequitable conduct would be futile").)

² Page citations to this document reflect the page numbers in the ECF footer on each page, rather than Plaintiffs' numbering convention (which has an unnumbered cover page that the ECF system denominates as page one).

in procuring the patents-in-suit. Specifically, the named inventors, through their attorney, knowingly submitted false arguments to the Patent Examiner, and also failed to provide that Examiner with their own research results that exposed those arguments as being false . . . with the intent to deceive [that] Examiner into allowing the patent claims." (Docket Entry 62 at 2-3.) Defendants set out their inequitable conduct allegations in 13 paragraphs consisting of approximately four and a half, 21-line pages of typed material. (Docket Entry 62-1 at 8-12.)

II. DISCUSSION

In this discussion, the Court considers whether it should deny Defendants' request to add the proposed inequitable conduct defense/counterclaim on grounds of futility due to Defendants' alleged failure to properly plead such matters. For the reasons that follow, the Court concludes that Defendants' proposed amended answer should set out more detail as to the specific portions of the publications of the inventors of the '081 patent and the relationship those items bear to specific claims/limitations in the patents at issue. Because, however, the Court finds that Defendants' proposed inequitable conduct allegations provide Plaintiffs with substantial notice about these matters and otherwise satisfy the pleading requirements set out in Exergen Corp. v. Wal-Mart Stores, Inc., 575 F.3d 1312 (Fed. Cir. 2009), the Court will permit Defendants to supplement their motion for leave

to amend their answer with a revised amended answer that includes the appropriate additional details.

A. Standard for Adding Inequitable Conduct Defense/Claim

Given the current procedural posture of the case and Plaintiffs' refusal to consent, the Federal Rules of Civil Procedure provide that Defendants "may amend [their] pleading only with . . . the court's leave." Fed. R. Civ. P. 15(a)(2). Said rule further directs that "[t]he court should freely give leave when justice so requires." Id. Under this standard, the Court has some discretion, "but outright refusal to grant the leave without any justifying reason appearing for the denial is not an exercise of discretion." Foman v. Davis, 371 U.S. 178, 182 (1962). Reasons to deny leave to amend include "futility of amendment." Id.

"An amendment would be futile if the amended claim would fail to survive a motion to dismiss for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6)." Syngenta Crop Prod., Inc. v. EPA, 222 F.R.D. 271, 278 (M.D.N.C. 2004). The Court thus must assess whether Defendants have pleaded sufficient facts to state an inequitable conduct claim/defense. In making this assessment, this Court must follow the precedent of the United States Court of Appeals for the Federal Circuit in "resolving issues intimately related to substantive patent law" Hanamint Corp., Inc. v. Alliant Mktg. Group, LLC, 481 F. Supp. 2d 444, 449 (M.D.N.C. 2007) (internal quotation marks omitted).

In general, a motion to amend an answer "under Rule 15(a) is a procedural matter governed by the law of the regional circuit." Exergen Corp., 575 F.3d at 1317. In this circumstance, however, Plaintiffs' attack on the proposed amendment implicates substantive patent law because it asserts that "the proposed pleading fails to meet the requirements for pleading fraud under [Rule] 9(b) and [that] there is no set of facts that Defendants can plead to state a claim for fraud on the Patent Office" (Docket Entry 69 at 2). See Exergen Corp., 575 F.3d at 1317 (ruling that "[Federal Circuit] law, not the law of the regional circuit, [applies] to the question of whether inequitable conduct has been pleaded with particularity under Rule 9(b)" and citing Central Admixture Pharmacy Servs., Inc. v. Advanced Cardiac Solutions, P.C., 482 F.3d 1347, 1356 (Fed. Cir. 2007), for proposition that "whether inequitable conduct has been adequately pleaded is a question of Federal Circuit law because it 'pertains to or is unique to patent law'"').³

³ The special pleading requirements of Rule 9(b) (rather than the general pleading requirements of Rule 8(a)) apply to inequitable conduct defenses/claims because of their similarity to fraud claims. See Exergen, 575 F.3d at 1326 ("Inequitable conduct, while a broader concept than fraud, must be pled with particularity under Rule 9(b)." (internal brackets and quotation marks omitted)); Digital Control Inc. v. Charles Mach. Works, 437 F.3d 1309, 1315 (Fed. Cir. 2006) (noting that inequitable conduct defense/claim "was borne out of a series of Supreme Court cases in which the Court refused to enforce patents whereby the patentees had engaged in fraud in order to procure those patents" and that, in following the Supreme Court's lead in subsequent patent cases, federal courts "generally tended to apply a doctrine somewhat akin to that of common law fraud, albeit broader" (internal citations omitted)).

The Federal Circuit has defined the elements of an inequitable conduct claim or defense as follows:

(1) an individual associated with the filing and prosecution of a patent application made an affirmative misrepresentation of a material fact, failed to disclose material information, or submitted false material information; and (2) the individual did so with a specific intent to deceive the [United States Patent and Trademark Office, also known as the] PTO.

Id. at 1327 n.3. "A pleading that simply avers the[se] substantive elements of inequitable conduct, without setting forth the particularized factual bases for the allegation, does not satisfy Rule 9(b)." Id. at 1326-27. Instead, "in pleading inequitable conduct in patent cases, Rule 9(b) requires identification of the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO." Id. at 1327. "Moreover, although 'knowledge' and 'intent' may be averred generally, [the] pleading . . . must include sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO." Id. at 1328-29.

B. Analysis of Proposed Inequitable Conduct Defense/Claim

1. The Patent Application Process

To analyze the sufficiency of Defendants' inequitable conduct allegations, the Court looks first to the framework in which

relevant events occurred, the patent application process. Another court has summarized the initial phase of that process as follows:

An application for a patent must be submitted to the Director of the United States Patent and Trademark Office (PTO). A complete patent application includes: a specification including one or more claims; an oath or declaration that the applicant believes himself to be the original inventor of the process or invention to be patented; drawings, if necessary; and the prescribed filing fee, search fee, examination fee, and application size fee. A claim specification must contain a written description of the invention to be patented and the process of making and using it, in full, clear, concise, and exact terms such that any person skilled in the art to which it pertains could make and use it.

HTC Corp. v. IPCom GmbH & Co., KG, 671 F. Supp. 2d 146, 149 (D.D.C. 2009) (internal citations and quotation marks omitted).

From this application, the PTO (initially via a patent examiner) assesses the patentability of the proposed invention. "The Patent Act sets out the conditions of patentability in three sections: . . . Section 101 . . . relat[es] to utility and patent eligibility . . . , sections 102 and 103 . . . relat[e] to novelty and nonobviousness, respectively . . ." Aristocrat Technologies Australia Pty Ltd. v. International Game Technology, 543 F.3d 657, 661 (Fed. Cir. 2008) (citing Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 12 (1966)). Accord Diamond v. Diehr, 450 U.S. 175, 189-91 (1981) ("Section 101 . . . is a general statement of the type of subject matter that is eligible for patent protection Specific conditions for patentability follow and § 102 covers in detail the conditions relating to novelty . . . [whereas

detailed conditions for] nonobviousness [are established] under § 103."). In evaluating novelty and nonobviousness, the PTO scrutinizes the relationship between the proposed invention and existing devices and/or knowledge ("prior art" in patent-speak). See generally Labounty Mfg., Inc. v. United States Int'l Trade Com'n, 958 F.2d 1066, 1071 (Fed. Cir. 1992) ("Section 102(b) may create a bar to patentability either alone, if the device [previously available to the public] is an anticipation of the later claimed invention or, in conjunction with [Section] 103, if the claimed invention would have been obvious from the [previously available] device in conjunction with the prior art." (internal citation omitted)); Black's Law Dict. 1193 (6th ed. 1990) (defining term "prior art" as "any relevant knowledge, acts, descriptions and patents which pertain to, but predate, invention in question").

The patent application process moves forward in a dynamic and interactive fashion as the PTO may reject aspects of an application (or "claims"⁴) and the applicant may respond: "Thus the patent examiner and the applicant, in the give and take of rejection and response, work toward defining the metes and bounds of the invention to be patented." In re Buszard, 504 F.3d 1364, 1366-67 (Fed. Cir. 2007). See also ICN Photonics, Ltd. v. Cynosure, Inc., 73 Fed. Appx. 425, 429 (Fed. Cir. 2003) ("Often, patent applicants

⁴ "In patent law, a claim is an assertion of what the invention purports to accomplish, and claims of a patent define the invention . . ." Black's Law Dict. 247 (6th ed. 1990).

amend their claims during the patent application process to more narrowly define their invention by including in the claims some detail of their invention not present in the prior art cited by the examiner"). During this entire process, "[a]pplicants for patents are required to prosecute patent applications in the PTO with candor, good faith, and honesty. This duty extends also to the applicant's representatives. A breach of this duty constitutes inequitable conduct." Molins PLC v. Textron, Inc., 48 F.3d 1172, 1178 (Fed. Cir. 1995) (internal citations and footnote omitted). Importantly, for the parties herein, an otherwise valid "patent may be rendered unenforceable for inequitable conduct," Trading Technologies Int'l, Inc. v. eSpeed, Inc., 595 F.3d 1340, 1362 (Fed. Cir. 2010). See Li Second Family Ltd. Partnership v. Toshiba Corp., 231 F.3d 1373, 1380 (Fed. Cir. 2000) (noting that "[i]nformation concealed from the PTO may be material even though it would not invalidate the patent" in affirming district court's ruling declaring patent unenforceable due to inequitable conduct).

2. Defendants' Allegations of Inequitable Conduct

As noted above, in the instant case, Defendants initially answered Plaintiffs' patent infringement action by asserting, inter alia, that all claims in four of Plaintiffs' underlying patents, including the '081 patent, were invalid for failure to comply with patent laws, including specifically Sections 101 through 103. As a result, the issue of whether the '081 patent satisfied the novelty

and nonobviousness requirements already has been joined in this litigation, thus bringing the parties' focus back onto the same ground over which Plaintiffs traveled in prosecuting the '081 patent application. By their proposed amendment, however, Defendants seek to expand the nature of this inquiry to include an examination of whether Plaintiffs committed inequitable conduct in connection with the underlying '081 patent application process.⁵

Defendants' non-conclusory factual allegations on that score include the following:

1) the patent examiner rejected "pending claims 37, 39-44, 46-50, and 53-55 in the '081 patent application . . . under [Section] 102(b) as being anticipated by Zamierowski WO '795, and . . . by Chariker, et al., . . . [and] further rejected certain claims under [Section] 103 based on these same references" (Docket Entry 62-1 at 8 (internal quotation marks omitted));

2) the '081 patent applicants, Drs. Louis Argenta and Michael Morykwas (the "Doctors"), through Donald Piper (the attorney prosecuting the '081 patent), submitted to the patent examiner a response "distinguish[ing] the Zamierowski WO '795 and Chariker prior art by amending certain claims to recite the limitation that

⁵ Defendants allege that "[t]he '081 patent is the parent patent for [the other three patents at issue] and all four patents are closely related and cover the same alleged invention, namely the treatment of a wound with negative pressure therapy." (Docket Entry 62-1 at 9.) For convenience, the discussion that follows generally will refer only to the '081 patent, although Defendants' proposed inequitable conduct defense/counterclaim encompasses all four patents at issue (through their common link to the '081 "parent" patent).

the negative pressure for healing wounds that is created by the claimed device is 'between about 0.1 and 0.99 atmospheres'" (with "0.1 atmospheres, when converted into . . . millimeters of mercury (mm Hg), equal[ing] approximately 80 mm Hg") (id. at 9);

3) in said response, the Doctors "characterized the Zamierowski WO '795 prior art as disclosing pressures from 0.08-0.10 atmospheres (which they equated to 60-80 mm Hg), which they stated is only useful for 'fluid introduction and drainage devices,' and not for devices 'for directly promoting wound healing'" and "contrasted the amended claims from that prior art by arguing that 'the use of negative pressures [0.1-0.99 atmospheres] in accordance with the present invention is critical to obtain the beneficial effects of the invention'" (id. (brackets as in Defendants' proposal) (Defendants' emphasis in internal quotations omitted));

4) in said response, the Doctors "further argued that 'the range [of pressure in Zamierowski WO '795] would be different than the workable range in the present invention because a lower pressure is required to drain fluid from or introduce fluid into a wound (about 0.08-0.10 atmospheres or less) than to promote the healing of the wound by the application of a negative pressure to the wound (about 0.1-0.99 atmospheres)'" (id. at 9-10 (brackets as appearing in Defendants' proposed pleading));

5) in said response, the Doctors "made the same distinction of the Chariker prior art, relying on the 'between about 0.1 and 0.99

atmospheres' amendment to argue that: 'In sharp contrast to [their] claimed invention, Chariker et al. relates to a wound drainage device and not to a device for promoting wound healing'" (id. at 10 (Defendants' emphasis in internal quotations omitted));

6) "[f]ollowing these arguments, the Patent Examiner allowed the amended claims, and the '081 patent was issued" (id.);

7) before submitting the foregoing response, the Doctors "had successfully treated and healed wounds using pressures below 0.1 atmospheres (80 mm Hg) . . . [and] repeatedly reported successful treatment of wounds at pressures as low as 50 mm Hg" (id.);

8) "[i]n none of these publications did [the Doctors] call 50 mm Hg of pressure just 'drainage,' or state that greater than 80 mm Hg pressure was needed to treat wounds . . . [but] [i]nstead [the Doctors] consistently indicated that 50 mm Hg pressure was the lower limit for attaining treatment and healing of a wound - thus including within the range of pressures effective for treating wounds the same levels of pressure that [their] response admitted were disclosed by the prior art" (id. at 10-11);

9) "[e]ven though publications showing the[se] results . . . , and the results themselves, were available to [the Doctors] during the prosecution of the '081 patent, they were never disclosed to the '081 Patent Examiner" (id. at 11);

10) the Doctors "have both admitted, in deposition testimony given in prior litigations . . . that pressures less than 0.1

atmosphere (80 mm Hg) could be used to treat wounds . . . [and] that pressures as low as 50 mm Hg could be used to treat wounds," which admissions are "entirely consistent with their research and publications from before the[ir] response [to the PTO]" (id.); and

11) "despite receiving additional research confirmation that negative pressures below 80 mm Hg could be used to treat wounds, [the Doctors] never retracted their false and misleading arguments, and instead continued to reiterate them repeatedly to the Examiners for [the three other] closely related patents" (id. at 12).

3. Applying the Who, What, When, Where, and How Test

As noted above, in assessing the sufficiency of the foregoing allegations, this Court must follow the Federal Circuit's directive that, "in pleading inequitable conduct in patent cases, Rule 9(b) requires identification of the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO." Exergen Corp., 575 F.3d at 1327 (emphasis added).

According to Plaintiffs, "Defendants have utterly failed to meet the 'what' and 'where' requirements set forth by the Federal Circuit." (Docket Entry 69 at 5.) Plaintiffs correctly quote the Federal Circuit's command that, to make out the "what" and "where" elements, a litigant must "'identify which claims, and which limitations in those claims, the withheld references are relevant to, and where in those references the material information is found . . .'" (Id. (quoting Exergen Corp., 575 F.3d at 1329) (emphasis

omitted).) As to the first part of this formulation, Plaintiffs assert that "Defendants' proposed answer is devoid of any citation to specific claims, much less specific limitations in any such claims. Rather [they] vaguely state that 'all four patents are closely related and cover the same alleged invention' and 'contain similar claims.'" (*Id.*) In fact, however, in one of the excerpts quoted above, Defendants' proposal does identify specific claims as to the '081 patent that the patent examiner rejected, which rejection Plaintiffs allegedly later engaged in inequitable conduct to have overturned. (See Docket Entry 62-1 at 8 (referencing "pending claims 37, 39-44, 46-50, and 53-55 in the '081 patent application").) Although Defendants could have made a clearer statement linking the alleged inequitable conduct they describe to those previously-identified claims (and/or the related limitations), the Court cannot agree that, read in context, "Defendants' proposed answer is devoid of any citation to specific claims . . . [or] limitations in any such claims."

As to the second portion of their "what" and "where" argument, Plaintiffs state that "[t]he proposed amended answer is also devoid of any citation to the references supposedly omitted. Rather, the Defendants vaguely refer to 'these publications' in which the [Doctors] 'reported successful treatment of wounds.' There is no specific listing of 'these publications,' much less any page citations indicating where in 'these publications' any supposedly

material information exists." (Docket Entry 69 at 5.) Plaintiffs cite no authority regarding the degree of specificity that a litigant must provide when alleging that a patent applicant's own prior publications contained material information kept from the patent examiner.⁶ Nor do Plaintiffs address the fact that (in the excerpts quoted above) Defendants provide fairly specific details about the nature of the information in the admittedly unnamed publications they reference. Given that the Doctors allegedly composed the publications at issue, it would seem that the provision of such details should suffice to give Plaintiffs adequate notice of this aspect of the inequitable conduct defense/counterclaim, particularly given that the Doctors appear to be (or at least to have been) employees of at least one of the Plaintiffs.

Under these circumstances, the Court finds that Defendants have provided Plaintiffs with substantial notice as to the "what" and "where" components of Defendants' instant defense/counterclaim. To the extent that Defendants fall short, the Court would describe said shortcomings as too technical and readily remediable to warrant denial of the proposed amendment as futile (for failure to satisfy Rule 9(b)'s heightened pleading requirement). Instead, the Court would elect to afford Defendants an opportunity to correct

⁶ The Court found one post-Exergen Corp. case in which the litigant asserting the inequitable conduct defense apparently did identify the specific publications authored by the inventors that contained allegedly undisclosed material information. See Aerocrine AB v. Apieron Inc., Civ. No. 08-787-LPS, 2010 WL 1225090, at *5 (D. Del. Mar. 30, 2010) (unpublished). Said court did not describe that level of detail as a necessary condition to satisfying Rule 9(b).

defects of this sort in order to apply Rule 9(b) in a manner consistent with the overarching goal of promoting merits-based resolution of claims. See United States v. Moradi, 673 F.2d 725, 727 (4th Cir. 1982) ("[T]he clear policy of the Rules is to encourage dispositions of claims on their merits")⁷

Plaintiffs next argue that Defendants "have failed to meet the 'why' and 'how' requirements set forth by the Federal Circuit." (Docket Entry 69 at 6.) The Federal Circuit's basic formulation of the inequitable conduct pleading test does not include a "why" component. See Exergen Corp., 575 F.3d at 1327 ("[I]n pleading inequitable conduct in patent cases, Rule 9(b) requires identification of the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO." (emphasis added)). However, Plaintiffs properly quote a later portion of said opinion in which the Federal Circuit appends a "why" requirement to the "how" element. (Docket Entry 69 at 6 ("The *Exergen* panel stated that the pleading must 'explain both "why" the withheld information is material and not cumulative, and "how" an examiner would have used this information in assessing patentability of the claims.''" (quoting Exergen Corp., 575 F.3d at 1329-30) (Plaintiffs' emphasis in internal quotations omitted)..)

⁷ At least one court has taken a similar approach in a similar context. See Semiconductor Energy Lab. Co., Ltd. v. Samsung Elec. Co., Ltd., No. 09-CV-01-bbc, 2010 WL 55847, at *12 (W.D. Wis. Jan. 5, 2010) (unpublished).

As to these aspects of the inequitable conduct pleading test, Plaintiffs assert that Defendants have offered "no explanation of why the 'publications' supposedly withheld are material, or how the Patent Examiner would have used information contained therein to assess the patentability of any particular claims." (*Id.*) The Court does not agree, but instead finds that Defendants have set out substantial factual allegations that show materiality, including the use a reasonable patent examiner would have made of the allegedly undisclosed information. Specifically, Defendants have alleged the following chain of events:

- 1) the patent examiner rejected specific claims within the '081 patent on the ground that specific items of prior art anticipated and/or rendered obvious the Doctors' proposed invention (Docket Entry 62-1 at 8);
- 2) the Doctors responded to this rejection by amending their claims and otherwise making statements to emphasize a particular feature of their system supposedly distinct from the specified prior art (i.e., the pressure levels employed) (*id.* at 9-10); and
- 3) the Doctors failed to disclose the fact that their own publications contained research showing that the cited pressure levels did not constitute a critical distinction (*id.* at 10-11).

For pleading purposes, these allegations make out the materiality element underlying the "how" and "why" questions cited by Plaintiffs. Specifically, the allegations tend to show that the

prior art cited by the patent examiner does anticipate and render obvious the proposed invention (as the patent examiner initially found) because the Doctors' research undercuts the significance of the amendment the Doctors proposed to distinguish the cited prior art. A reasonable patent examiner would have used the undisclosed information to assess whether the distinction tendered by the Doctors to defeat the anticipation and obviousness findings was in fact significant, and thus whether to stand by the prior rejections or to allow issuance of a patent.⁸ The Court finds support for this analysis in Cargill, Inc. v. Canbra Foods, Ltd., 476 F.3d 1359, 1364 (Fed. Cir. 2007) (affirming inequitable conduct finding where inventor emphasized distinction between capacity of prior and new device to perform function, but failed to disclose research contradicting that suggestion, because "it is quite certain that a 'reasonable examiner' would consider such test data to be important in deciding whether to allow the patents to issue").

Under these circumstances, the Court determines that, but for the need to provide supplemental details identifying the specific titles of the Doctors' publications at issue (as well as some page range, heading, or section within those publications) and to

⁸ In this regard, Defendants need not allege facts sufficient to show that the undisclosed information actually would have established the proposed invention's invalidity (as anticipated or obvious), because "[i]nformation concealed from the PTO may be material even though it would not invalidate the patent." Li Second Family, 231 F.3d at 1380. To the contrary, "[i]nformation is deemed material if there is a substantial likelihood that a reasonable examiner would have considered the information in deciding whether to allow the application to issue as a patent." Id. at 1379.

clarify the specific claims and/or limitations within the patents at issue to which such specific publications relate, Defendants have satisfied the Federal Circuit's "who, what, when, where, and how" test for pleading inequitable conduct.⁹ The Court further concludes that, as to the foregoing matters, because Defendants gave Plaintiffs substantial notice and should be able to remedy the technical shortfall, a finding of futility is unwarranted.

4. Scienter and Related Arguments

In Exergen Corp., in addition to adopting the "who, what, when, where, and how" test, the Federal Circuit stated the following: "[A]lthough 'knowledge' and 'intent' may be averred generally, [the] pleading . . . must include sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO." Exergen Corp., 575 F.3d at 1328-29.

According to Plaintiffs, "Defendants cannot plead that [the Doctors] made a knowingly false statement because all statements made by [the Doctors] concerning the amount of reduced pressure that could be used in the invention were true." (Docket Entry 69 at 6-7.) In support of this assertion, Plaintiffs declare that, in

⁹ Plaintiffs do not present any argument as to the "who" or "when" components of the Exergen Corp. test. Moreover, the Court's review reflects that Defendants have included sufficient allegations on these points.

connection with the '081 patent, the Doctors "truthfully stated to the Patent Examiner that 'the use of negative pressures in accordance with the present invention is critical to obtain the beneficial effects of the invention.'" (*Id.* at 7.) This argument ignores the fact that, although said sentence does not specify a particular "degree" of pressure, it must be read in the context of other statements the Doctors allegedly made that indicated the degree of pressure required for use "in accordance with present invention" was of a certain magnitude that differentiated their system from the prior art cited by the patent examiner.

Further, Defendants' inequitable conduct allegations focus on the failure of the Doctors to disclose information that called into doubt the Doctors' attempt to distinguish their system from prior devices by describing their approach as one that depended on higher pressure levels to provide wound healing, whereas the prior art operated at lower pressure levels and performed drainage, not healing. (Docket Entry 62-1 at 9-11.) At a minimum, Defendants' allegations in this regard sufficiently allege that the Doctors knowingly withheld material information from the PTO. Because inequitable conduct claims/defenses encompass not only knowing false statements, but also knowing failures to disclose material information, Plaintiffs' arguments on this point lack merit.

In several places in their brief, Plaintiffs offer a further argument related to the above-cited quotation from the '081 patent

application (i.e., that "the use of negative pressures in accordance with the present invention is critical to obtain the beneficial effects of the invention"). Specifically, Plaintiffs assert that Defendants' allegations "misquote" (or, more accurately, distort) said sentence by construing it, in light of other statements they attribute to the Doctors, to include by implication a pressure restriction of 0.1-0.99 atmospheres (which implication Defendants express by bracketing such information within the sentence). (Docket Entry 69 at 3, 6, 7, 9-11.)

Plaintiffs attempt to bolster their position in this regard by pointing to statements the Doctors allegedly made in connection with a later patent application and in describing the pump that was required for the '081 patent. According to Plaintiffs, these matters demonstrate that "Defendants' purported allegation that [the Doctors] stated 'negative pressures [0.1-0.99 atmospheres]' is critical to the invention is not only a blatantly false quotation, but [also] entirely inconsistent with what [the Doctors] repeatedly stated to the Patent Examiner in the very specifications of the Patents themselves." (*Id.* at 7.) (*Accord id.* at 3 ("Without explanation, the Defendants took the bracketed numerical pressure range from a different paragraph of [the Doctors'] responsive document and invented a new quotation . . . [while] conveniently omitt[ing] statements by [the Doctors] in the Patent specifications themselves in which [the Doctors] clearly disclosed that pressures

lower than 0.1 atmospheres had been used."), 11 ("Not only have the Defendants misquoted [the Doctors] . . . , but they have omitted similar truthful statements [the Doctors] made").)

All of these arguments boil down to the following contention from Plaintiffs: "Since the Defendants 'facts' are demonstrably false, their theory of inequitable conduct is frivolous, and thus the requested amendment would be futile." (Id. at 3.) The problem for Plaintiffs is that the alleged "falsity" of Defendants' factual allegations cannot be assessed at the pleading stage.

Other litigants have tried similar attacks on proposed inequitable conduct claims/defenses since Exergen Corp. and courts have rejected them. See, e.g., Lincoln Nat'l Life v. Transamerica Fin. Life Ins. Co., No. 1:08CV135, 2009 WL 4547131, at *2-4 (N.D. Ind. Nov. 25, 2009) (unpublished) ("Rule 9(b) does not require that the defendant definitively prove the merits of its claim. What is determinative here is that the plaintiff was given fair notice of the basis for the defendant's inequitable conduct defense. . . . It remains to be seen whether the Defendants' inequitable conduct claim will survive a motion for summary judgment. As the Plaintiff repeatedly argues, the Defendants have not proved that any inequitable conduct occurred. That, however, is not the point of notice pleading. The Court simply holds that the Defendants' pleading meets the *Exergen* who, what, when, where, and how standard.") (internal brackets and quotation marks omitted));

Synventive Molding Solutions, Inc. v. Husky Injection Molding Sys., Inc., No. 2:08CV136, 2009 WL 3172740, at *3 (D. Vt. Oct. 1, 2009) (unpublished) ("Synventive protests that the (sic) Husky has misstated the claim elements and the structure and functionality of the prior art These arguments attack the merits of Husky's inequitable conduct claim, not whether the claim has been adequately pled. . . . Although Synventive disputes the meaning and the significance of the [allegedly withheld] documents' use of [certain] term[s] . . . there is no real dispute that Husky has identified where it believes the material omission may be found. . . . Whether or not Husky's counterclaim for unenforceability due to inequitable conduct can survive summary judgment awaits the appropriate motion. The Court merely holds that Husky has adequately pled an affirmative defense and counterclaim based on inequitable conduct before the PTO.").

Similarly, in this case, Plaintiffs' citations of alleged aspects of their filings before the PTO that support their view of the truthfulness and completeness of the Doctors' representations during the '081 patent application process constitute matters to be weighed at another stage of the proceedings against the other portions of such filings that Defendants allege show knowing withholding of material information. The existence of reasonable inferences of non-culpable conduct does not affect the viability of an inequitable conduct claim/defense at the pleading stage. See

The Braun Corp. v. Vantage Mobility Int'l, LLC, No. 2:06-CV-50-JVB-PRC, 2010 WL 403749, at *8 (N.D. Ind. Jan. 27, 2010) (unpublished). Plaintiffs' scienter and related arguments thus do not foreclose Defendants' proposed inequitable conduct defense/counterclaim.¹⁰

III. CONCLUSION

Plaintiffs have not shown that Defendants' proposed inequitable conduct defense/counterclaim is futile. To the contrary, the Court concludes that, but for certain matters that the Court deems readily remediable, Defendants' proposal satisfies the pleading standard set by the Federal Circuit for such matters.

¹⁰ As a final matter, Plaintiffs rely on portions of Exergen Corp. in which the Federal Circuit barred litigants from relying solely on conclusory allegations of "specific intent" made on "information and belief" to assert that Defendants' proposed inequitable conduct defense/counterclaim fails as a matter of law. (Docket Entry 69 at 7-9.) As quoted and discussed above, Defendants have made detailed allegations showing that: 1) the Doctors sought to overcome the patent examiner's rejection of their proposed invention as anticipated and obvious by making responses that reasonably can be read as distinguishing their system from prior systems based on the amount of pressure utilized; 2) the Doctors' own prior published research called into question any such distinction; and 3) the Doctors did not disclose that prior research. The Court finds that such factual allegations distinguish Defendants' pleading from the one at issue in Exergen Corp. and sufficiently make out, at the pleading stage, the knowledge and materiality elements of inequitable conduct. Further, although other inferences also may be possible, it is "reasonable to infer that the inventors deliberately withheld this material [information] from the PTO, based on the allegations of knowledge and materiality. Whether these allegations of inequitable conduct by [the Doctors] (like other similar allegations discussed in this Order) are ultimately provable or accurate is not an issue before the Court today." Aerocrine AB, 2010 WL 1225090, at *11. See also Li Second Family, 231 F.3d at 1381 ("Intent to deceive the PTO need not be proven by direct evidence. Indeed, direct proof of wrongful intent is rarely available but may be inferred [at the disposition stage] from clear and convincing evidence of the surrounding circumstances." (internal brackets and quotation marks omitted)); Konami Digital Entertainment Co., Ltd. v. Harmonix Music Sys., Inc., No. 6:08CV286-JDL, 2009 WL 5061812, at *2 (E.D. Tex. Dec. 14, 2009) (unpublished) ("The Federal Circuit teaches that these allegations need not be a 'smoking gun,' but rather sufficient grounds to infer the requisite knowledge and intent."). Any other approach would eviscerate the rule that "intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b).

IT IS THEREFORE ORDERED that a ruling on Defendants' Motion for Leave to File Their Amended Answer (Docket Entry 62) is deferred to allow Defendants an opportunity to correct technical deficiencies identified in this Memorandum Opinion and Order.

IT IS FURTHER ORDERED that, by April 15, 2010, Defendants shall file a Supplement to their Motion for Leave to File Their Amended Answer with a revised version of the Amended Answer that includes the specific titles of the Doctors' publications at issue (as well as page ranges, headings, or like identifiers in those publications) and clarifies the specific claims and/or limitations within the patents at issue to which such publications relate.

IT IS FURTHER ORDERED that, by April 22, 2010, Plaintiffs shall file a memorandum stating any objections Plaintiffs have as to the sufficiency of any newly-alleged details in the revised proposed amended answer. Plaintiffs need not repeat the arguments they have raised to this point and are understood to maintain the positions stated in Plaintiffs' Brief in Opposition to Defendants' Motion for Leave to File Their Amended Answer (Docket Entry 69).

IT IS FURTHER ORDERED that Defendants shall not file any response or reply to Plaintiffs' memorandum without permission.

/s/ L. Patrick Auld
L. Patrick Auld
United States Magistrate Judge

April 8, 2010